

Appl. No. 09/996,555  
Atty. Dockel No. 8341  
Amdt. dated 5 November 2004  
Reply to Office Action of 25 August 2004  
Customer No. 27752

### REMARKS

#### AMENDMENTS TO THE CLAIMS

Claims 1-11 and 14-35 are pending in the application. Herein, Applicants amend Claims 1 and 11; cancel no Claims; and add new Claims 36-37, WHEREUPON Claims 1-11, and 14-37 remain to be examined. Authorization to pay the additional claims fees believed to be due is attached.

Claims 1 and 11 have been amended to more particularly point out and distinctly claim Applicants' invention by indicating that the invention "consist[s] essentially of" the elements (a), (b), and (c), as listed therein.

Claims 1 and 11 have also been amended to more particularly point out and distinctly claim Applicants' invention by deleting "directly", as required by the Office Action.

New Claim 36 has been added to more particularly point out and distinctly claim Applicants' invention by indicating preferred constituents for elements (a), (b), and (c) of the inventive compositions. Basis lies, at least, in the claims as originally filed.

New Claim 37 has been added to more particularly point out and distinctly claim Applicants' invention by claiming a method of delivering and releasing the preferred constituents of Claim 36. Basis lies, at least, in the claims as originally filed.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested. Applicants expressly reserve their right to pursue any unclaimed subject matter through one or more continuing applications.

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### WRITTEN DESCRIPTION

Claims 1-11 and 14-35 are rejected under 35 USC §112(1) as allegedly failing to comply with the written description requirement. The Examiner asserts that the recitation of applied "directly" in Claims 1 and 11 is not supported by the specification and thus, introduces new matter.

Without commenting on whether "directly" is supported or not, and merely to expedite prosecution, Applicants herein amend Claims 1 and 11 by deleting "directly" from them. As such, it is believed that this rejection is obviated and should properly be withdrawn.

### NOVELTY

Claims 1-4, 8-11, 14, 19-22 and 25 are rejected under 35 USC §102(b) as allegedly being anticipated by US 5,171,580 [herein "Iamartino"]. Applicants respectfully traverse the rejection as applied to the claims, as amended herein, for the reasons set forth below.

Iamartino discloses an orally administrable pharmaceutical preparation comprising three coating layers: an inner layer, an intermediate layer, and an outer layer (col. 3, Summary of the Invention). The inner layer comprises anionic polymers, including those derived from methacrylic acid and methyl methacrylate (col. 3, lines 37-39). The intermediate layer comprises gelling polymers including various cellulose or vinyl containing polymers (col. 3, lines 58-68). The outer layer comprises enteric materials, including among others, acrylic polymers such as anionic copolymers derived from methacrylic acid and methyl methacrylate (col. 4, lines 21-29). Importantly, the intermediate layer "is applied directly onto the first inner layer" (col. 4, lines 1-2). Thus, beginning at the innermost layer and moving outwardly, Iamartino has a [methacrylic acid and methyl methacrylate polymer] → [gelling polymer] → [methacrylic acid and methyl methacrylate polymer] arrangement.

Contrastingly, Applicants invention requires a pharmaceutical composition in a solid unit dosage form for oral administration consisting essentially of a therapeutically active agent and two layers: an inner layer and an outer layer (Claims 1 and 11). The inner layer comprises methacrylic acid and methyl methacrylate polymers. The outer layer comprises methacrylic acid, methyl methacrylate, ethyl methacrylate, and polyvinyl acetate phthalate polymers. Importantly, the outer layer "is applied to the inner coating layer". Thus, beginning at the innermost layer and moving outwardly, the invention has a [methacrylic acid and methyl methacrylate polymers] →

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[methacrylic acid, methyl methacrylate, ethyl methacrylate, and polyvinyl acetate phthalate polymers] arrangement. The inventive arrangement does not permit an intermediate layer, e.g. one comprising a gelling polymer to come between the invention's inner and outer coating layers.

The Examiner has asserted that Applicants use of the transition phrase "comprising" in Claims 1 and 11 does not exclude the presence of Iamartino's intermediate layer (Office Action, page 4, lines 17-19). Applicants gratefully acknowledge the telephone conversations that took place on 20 and 23 August 2004, between the Examiner and Applicant's undersigned attorney, in which the Examiner suggested that Claims 1 and 11 would be allowable if the transition phrase "comprising" was amended to read "consisting essentially of" in both claims, such language being sufficient to exclude Iamartino's intermediate layer.

Without commenting on whether "comprising" is sufficient to exclude Iamartino's intermediate layer or not, and merely to expedite prosecution, Applicants herein amend Claims 1 and 11 by deleting "comprising" and inserting --consisting essentially-- therefor. As such, it is believed that this rejection is obviated and should properly be withdrawn.

#### NON-OBVIOUSNESS

Claims 5-7, 16-18, and 26-35 are rejected under 35 USC §103(a) as allegedly being unpatentable over Iamartino. Applicants respectfully traverse the rejection as applied to the claims, as amended herein, for the reasons set forth below.

Applicants submit that neither the teaching of Iamartino generally, nor the passages cited by the Examiner, teaches or suggests all the claim limitations of Applicants' invention. In fact, at least because Iamartino requires its intermediate [gelling polymer] layer to be applied directly onto its first inner layer which comprises [methacrylic acid and methyl methacrylate polymer], Iamartino teaches away from Applicants' invention. Applicants submit that the teaching of Iamartino does not teach or suggest the oral administration to the gastrointestinal tract of a formulation comprising an outer layer comprising a pH dependent polymer that begins to dissolve in an aqueous medium at a pH of less than about 7, which are [methacrylic acid, methyl methacrylate, ethyl methacrylate, and polyvinyl acetate phthalate polymers] and an inner layer comprising [methacrylic acid and methyl methacrylate polymers], where such an outer layer "is applied to the inner coating layer".

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The Examiner has asserted that Applicants use of the transition phrase "comprising" in Claims 1 and 11 does not exclude the presence of Iamartino's intermediate layer (Office Action, page 7, lines 1-3).

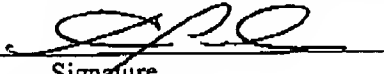
Again, without commenting on whether "comprising" is sufficient to exclude Iamartino's intermediate layer or not, and merely to expedite prosecution, Applicants herein amend Claims 1 and 11 (and all of the claims rejected as being allegedly obvious, by virtue of their dependence of either Claim 1 or 11 directly or indirectly) by deleting "comprising" and inserting --consisting essentially-- therefor. As such, it is believed that this rejection is obviated and should properly be withdrawn.

#### CONCLUSION

Applicants have made an earnest effort to place their application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-11, and 14-37. Early and favorable action in the case is respectfully requested. If there are remaining issues and the Examiner believes it would be prudent to do so, then she is invited to telephone the undersigned attorney to discuss them.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

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